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Biotechnology

Expert Panel Recommends Changes to GOC Regulatory Policy for GM Foods

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Report Highlights: An expert scientific panel, commissioned by the Canadian government, has released a report on the Regulation of Food Biotechnology in Canada which concludes that GM crops and foods in Canada should be subject to more rigorous testing, and that the level of government support for independent research on the safety of food biotechnology is inadequate. In response, the GOC has assured the public that the government will study the report in detail to determine how it can help to improve Canada's regulatory system for GM food products.

Includes PSD changes: No
Includes Trade Matrix: No
Unscheduled Report
Ottawa [CA1], CA

Summary:

In December 1999, Canada's federal departments of Health, Agriculture and Environment announced their intention to establish an expert panel to examine government regulation and future scientific developments in food biotechnology (see CA0011). In November 2000, Health Canada approached The Royal Society of Canada (The Canadian Academy of the Sciences and Humanities) to commission the expert panel to advise the GOC on the safety of new food products being developed through biotechnology. On February 5, 2001 the Expert Panel released their report entitled: *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada*. The Expert panel raised serious questions about the regulation of GM food and made 53 recommendations to the GOC, concluded that GM crops and foods in Canada should be subject to more rigorous testing, and that the level of government support for independent research on the safety of food biotechnology is inadequate. Although the GOC is not bound by the panel's recommendations, the GOC Ministers have assured the public that the government will study the report in detail to determine how it can help to improve Canada's regulatory system for GM food products and processes. The Expert Panel's Recommendations are listed at the end of this report along with the Internet sites for downloading the report and the associated press releases.

Canada's Health Minister, Alan Rock, put a positive spin on the Expert Panel's report saying that The Royal Society report provided recommendations which would help Canada to strengthen the genetically modified (GM) foods regulatory system to better meet future needs. "This report, like other reports on food biotechnology, (i.e., National Academy of Science in the United States, the American Medical Association Scientific Council, and the British Royal Society), does not raise concerns about the safety of GM foods currently in the marketplace", said Mr. Rock .

Royal Society of Canada Press Release

In its February 5, 2001 press release, entitled *Expert Panel Raises Serious Questions About the Regulation of GM Food*, the Royal Society of Canada stated:

> "...that if the scientific panel had its way, GM crops and foods (in Canada) would be more rigorously tested, the testing would be independently reviewed, and there would be a moratorium on GM fish grown in farms on Canada's coasts. These conclusions are among the fifty-three recommendations put forward by the Expert Panel. The Panel was also critical of the level of secrecy surrounding testing of new GM products, and recommended that external review of GM product approvals be introduced, as well as increased public access to the results of the tests.... the public needs to be confident that any deployment of GM products occurs only after thorough and objective assessment, and that provision of benefit for the public good in Canada remains the ultimate benchmark. The Panel was also strongly critical of the inadequate levels of government support for independent research on the safety of food biotechnology in Canada. The increasing domination of university research by the commercial interests of the researchers and their industry partners removes incentives for reliable scientific research on the safety of these products. Government regulators need a body of such research to protect the public interest and the environment, the Panel noted.
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> On the contentious issue of labeling of GM foods, the Panel concluded that mandatory labeling should be required only where there is scientific evidence of significant risks to certain members of the population, such as those with allergies. If thorough and appropriate testing were carried out then general mandatory labeling of all GM products would be unnecessary. The Panel suggested, however, that strong government support for voluntary labels is an effective way of providing consumer input into these issues, and encourages the Canadian regulatory agencies

responsible to establish guidelines for the regulation of reliable, informative voluntary labels.

End Royal Society press release excerpt.

Expert Panel Recommendations

Expert Panel's 53 Recommendations Concerning Underlying Policies and Principles Guiding the Regulation of Agricultural Biotechnology

The Panel recommends that approval of new transgenic organisms for environmental release, and for use as food or feed, should be based on rigorous scientific assessment of their potential for causing harm to the environment or to human health. Such testing should replace the current regulatory reliance on "substantial equivalence" as a decision threshold.

The Panel recommends that the design and execution of all testing regimes of new transgenic organisms should be conducted in open consultation with the expert scientific community.

The Panel recommends that analysis of the outcomes of all tests on new transgenic organisms should be monitored by an appropriately configured panel of "arms-length" experts from all sectors, who report their decisions and rationale in a public forum.

The Panel recommends the precautionary regulatory assumption that, in general, new technologies should not be presumed safe unless there is a reliable scientific basis for considering them safe. The Panel rejects the use of "substantial equivalence" as a decision threshold to exempt new GM products from rigorous safety assessments on the basis of superficial similarities because such a regulatory procedure is not a precautionary assignment of the burden of proof.

The Panel recommends that the primary burden of proof be upon those who would deploy food biotechnology products to carry out the full range of tests necessary to demonstrate reliably that they do not pose unacceptable risks.

The Panel recommends that, where there are scientifically reasonable theoretical or empirical grounds establishing a *prima facie* case for the possibility of serious harms to human health, animal health or the environment, the fact that the best available test data are unable to establish with high confidence the existence or level of the risk should not be taken as a reason for withholding regulatory restraint on the product.

As a precautionary measure, the Panel recommends that the prospect of serious risks to human health, of extensive, irremediable disruptions to the natural ecosystems, or of serious diminution of biodiversity, demand that the best scientific methods be employed to reduce the uncertainties with respect to these risks. Approval of products with these potentially serious risks should await the reduction of scientific uncertainty to minimum levels.

The Panel recommends a precautionary use of "conservative" safety standards with

respect to certain kinds of risks (e.g. potentially catastrophic). When "substantial equivalence" is invoked as an unambiguous safety standard (and not as a decision threshold for risk assessment), it stipulates a reasonably conservative standard of safety consistent with a precautionary approach to the regulation of risks associated with GM foods.

The Panel recommends that Canadian regulatory agencies and officials exercise great care to maintain an objective and neutral stance with respect to the public debate about the risks and benefits of biotechnology in their public statements and interpretations of the regulatory process.

The Panel recommends that the Canadian regulatory agencies seek ways to increase the public transparency of the scientific data and the scientific rationales upon which their regulatory decisions are based.

The Panel recommends that the Canadian regulatory agencies implement a system of regular peer review of the risk assessments upon which the approvals of genetically engineered products are based. This peer review should be conducted by an external (non-governmental) and independent panel of experts. The data and the rationales upon which the risk assessment and the regulatory decision are based should be available to public review.

The Panel recommends that the Canadian Biotechnology Advisory Commission (CBAC) undertake a review of the problems related to the increasing domination of the public research agenda by private, commercial interests, and make recommendations for public policies that promote and protect fully independent research on the health and environmental risks of agricultural biotechnology.

Recommendations Concerning Regulations and Guidelines

The Panel recommends that federal regulatory officials in Canada establish clear criteria regarding when and what types of toxicological studies are required to support the safety of novel constituents derived from transgenic plants.

The Panel recommends that, in view of the availability of suitable alternative markers, antibiotic resistance markers should not be used in transgenic plants intended for human consumption.

The Panel recommends that approvals should not be given for GM products with human food counterparts that carry restrictions on their use for non-food purposes (e.g. crops approved for animal feed but not for human food). Unless there are reliable ways to guarantee the segregation and recall if necessary of these products, they should be approved only if acceptable for human consumption.

The Panel recommends that the Canadian Food Inspection Agency (CFIA) develop detailed guidelines describing the approval process for transgenic animals intended for (a) food production or (b) other non-food uses, including appropriate scientific criteria for assessment of behavioral or physiological changes in animals resulting from genetic modification.

The Panel recommends that companies applying for permission to release a GM organism into the environment should be required to provide experimental data (using ecologically meaningful experimental protocols) on all aspects of potential environmental impact.

The Panel recommends that an independent committee should evaluate both the experimental protocols and the data sets obtained before approvals of new plants with novel traits are granted.

The Panel recommends that standard guidelines should be drawn up for the long-term monitoring of development of insect resistance when GM organisms containing "insecticidal" products are used, with particular attention to pest species known to migrate over significant distances.

The Panel recommends that a moratorium be placed on the rearing of GM fish in aquatic netpens.

The Panel recommends that approval for commercial production of transgenic fish be conditional on the rearing of fish in land-based facilities only.

Recommendations Concerning the Regulatory Process

The Panel recommends that regulatory authorities establish a scientific rationale that will allow the safety evaluation of whole foods derived from transgenic plants. In view of the international interest in this area, the Panel further recommends that Canadian regulatory officials collaborate with colleagues internationally to establish such a rationale and/or to sponsor the research necessary to support its development.

The Panel recommends development of mechanisms for after-market surveillance of GM foods incorporating any novel protein.

The Panel recommends that the appropriate government regulatory agencies have in place a specific, scientifically sound and comprehensive approach for ensuring that adequate allergenicity assessment will be performed on GM foods.

The Panel recommends that all assessments of GM foods, which compare the test material with an appropriate control, should meet the standards necessary for publication in a peer-reviewed journal, and all information relative to the assessment should be available for public scrutiny. The data should include the full nutrient composition (Health Canada, 1994), an analysis of any anti-nutrient and, where applicable, a protein evaluation such as that approved by the United Nations Food and Agriculture Organization (FAO).

The Panel recommends that protocols should be developed for the testing of future genetically engineered foods in experimental diets.

The Panel recommends that the Canadian Nutrient File should be updated to include the composition of genetically engineered foods and be readily available to the public.

The Panel recommends that the approval process for transgenic animals include a rigorous assessment of potential impacts on three main areas:

1) the impact of the genetic modifications on animal health and welfare;
2) an environmental assessment that incorporates impacts on genetic diversity and sustainability; and
3) the human health implications of producing disease-resistant animals or those with altered metabolism (e.g. immune function).

The Panel recommends that the tracking of transgenic animals be done in a manner similar to that already in place for pedigree animals, and that their registration be compulsory.

The Panel recommends that transgenic animals and products from those animals that have been produced for non-food purposes (e.g. the production of pharmaceuticals) not be allowed to enter the food chain unless it has been demonstrated scientifically that they are safe for human consumption.

The Panel recommends that the use of biotechnology to select superior animals be balanced with appropriate programs to maintain genetic diversity, which could be threatened as a result of intensive selection pressure.

The Panel recommends that changes in susceptibility of genetically engineered plants to toxin-producing microbes, and the potential transfer of these to the animal and the food supply, be evaluated as part of the approval process.

The Panel recommends that a data bank listing nutrient profiles of all GM plants that potentially can be used as animal feeds be established and maintained by the federal government.

The Panel recommends that university laboratories be involved in the validation of the safety and efficacy of GM plants and animals.

The Panel recommends that Environment Canada and the Canadian Food Inspection Agency establish an assessment process and monitoring system to ensure safe introductions of GM organisms into Canada, according to the intent of the Canadian Environmental Protection Act.

The Panel recommends that all ecological information on the fate and effects of transgenic biotechnology products on ecosystems required under existing regulations should be generated and made available for peer review.

The Panel recommends the carrying out of exhaustive, long-term testing for ecological effects of biotechnology products that pose environmental risks, especially with respect to persistence of the organism or a product of the organism, persistent effects on biogeochemical cycles, or harmful effects resulting from horizontal gene transfer and selection.

The Panel recommends that, in evaluating environmental risks, scientific emphasis should be placed on the potential effects of selection operating on an introduced organism or on genes transferred to natural recipients from that organism.

The Panel recommends that the history of domestication, and particularly the time period and

intensity of artificial selection, of GM plants should be taken into account when assessing potential environmental impacts. Species with a short history of domestication should receive particularly close scrutiny because they are more likely to pose environmental risks.

The Panel recommends that environmental assessments of GM plants should pay particular attention to reproductive biology, including consideration of mating systems, pollen flow distances, fecundity, seed dispersal and dormancy mechanisms. Information on these life-history traits should be obtained from specific experiments on the particular GM cultivar to be assessed, not solely from literature reports for the species in general.

The Panel recommends that environmental assessments of GM plants should not be restricted to their impacts on agroecosystems but should include an explicit consideration of their potential impacts on natural and disturbed ecosystems in the areas in which they are to be grown.

The Panel recommends that research data from experiments conducted by industry on the potential environmental impacts of GM plants used in Canadian Environmental Protection Agency assessments should be made available for public scrutiny.

The Panel recommends that potential risks to the environment posed by transgenic fish be assessed not just case-by-case, but also on a population-by-population basis.

Recommendations Concerning Scientific Capacity for the Regulation of Food Biotechnology

The Panel recommends that the Canadian government support research initiatives to increase the reliability, accuracy and sensitivity of current methodology to assess allergenicity of a food protein, as well as efforts to develop new technologies to assist in these assessments.

The Panel recommends the strengthening and development of infrastructures to facilitate evaluation of the allergenicity of GM proteins. This could include development of a central bank of serum from properly screened individuals allergic to proteins which might be used for genetic engineering, a pool of standardized food allergens and the novel GM food proteins or the GM food extracts, maintenance and updating of allergen sequence databases, and a registry of food-allergic volunteers.

The Panel recommends that federal and provincial governments ensure adequate public investment in university-based genomic research and education so that Canada has the capacity for independent evaluation and development of transgenic technologies.

The Panel recommends that a national research program be established to monitor the long-term effects of GM organisms on the environment, human health, and animal health and welfare.

The Panel recommends that a detailed analysis be undertaken of the expertise needed in Canada to evaluate environmental effects of new biotechnology products and, if the appropriate expertise

is found to be lacking, resources be allocated to improving this situation.

The Panel recommends that a federally funded multidisciplinary research initiative be undertaken on the environmental impacts of GM plants. Funds should be made available to scientists from all sectors (industry, government and university) with grant proposals subject to rigorous peer review.

The Panel recommends the establishment of comprehensive research programs devoted to the study of interactions between wild and cultured fish. Reliable assessment of the potential environmental risks posed by transgenic fish can be undertaken only after extensive research in this area.

The Panel recommends that identification of pleiotropic, or secondary, effects on the phenotype resulting from the insertion of single gene constructs into GM organisms be a research priority.

The Panel recommends that Canada develop and maintain comprehensive public baseline data resources that address the biology of both its major agroecosystems and adjacent biosystems.

The Panel recommends that Canada develop state-of-the-art genomics resources for each of its major crops, farm animals and aquacultured fish, and use these to implement effective methodologies for supporting regulatory decision making.

GOC Reaction

In its February 5, 2001 press release, entitled: *Government of Canada Welcomes Royal Society Expert Scientific Panel Report On the Future of Food Biotechnology*, the GOC stated:

> "The Royal Society has provided us with advice on how to continue to ensure the health and safety of Canadians through a sound regulatory and assessment process for products derived from biotechnology," said Health Minister Allan Rock. "Strengthening the regulatory system to meet future demands is a priority, and these recommendations will help us in that objective."
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> "Canada needs to remain on the leading edge of new scientific developments, so that our food supply continues to be one of the safest in the world," said Minister of Agriculture and Agri-Food, Lyle Vanclief. "Our scientists will study this report in detail to determine how it can help to improve Canada's regulatory system into the 21st century."
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> Environment Minister David Anderson said, "I will continue to work with my colleagues to ensure that the decisions we make concerning genetically modified products are based on sound science and that Canada’s environment is protected."
>
> The health and safety of Canadians, and the safety of the environment are of paramount concern for the Government of Canada in setting guidelines and standards the food industry must meet before a genetically modified food is permitted on the Canadian market.

Under the Food and Drugs Act, Health Canada conducts a thorough safety assessment of each new product before it can be sold in Canada. The Canadian Food Inspection Agency (CFIA) also has responsibility for the regulation of products derived from biotechnology including plants, animal feeds and animal feed ingredients, fertilizers and veterinary biologics.

Under the new Canadian Environmental Protection Act (CEPA), Environment Canada and Health Canada conduct risk assessments of new substances including biotechnology products, to determine if there are adverse effects to the environment or human health, prior to their import into or manufacture in Canada.

The Government of Canada is committed to the on-going process of ensuring that its regulation of foods derived from biotechnology is appropriate for the state of the science and the types of food and plant products that are being developed through research. To that end, the government has allocated $90 million in Budget 2000 specifically to enhance the regulatory system for products of biotechnology.

The advice of the Expert Scientific Panel will be complemented by recommendations from the Canadian Biotechnology Advisory Committee on broad biotechnology policy issues that are expected this Spring.

End GOC press release excerpt.

Listing of URLs for Electronic Copies of Reports & Press Releases

Canadian Food Inspection Agency:

http://www.cfia-acia.agr.ca/english/corpaffr/newcom/20010205e.shtml

Press Release: Government of Canada Welcomes Royal Society Expert Scientific Panel Report On the Future of Food Biotechnology

Royal Society of Canada: http://www.rsc.ca/foodbiotechnology/indexEN.html

Expert Panel on the Future of Food Biotechnology, Press Statement - .pdf file
Report of the Expert Panel on the Future of Food Biotechnology
Full report - .pdf file
Table of Contents and Executive Summary - .pdf file
January 30, 2001: Release of the Expert Panel report: February 5, 2001 - .pdf file
Press release of February 17, 2000 announcing panel - .pdf file
List of panel members and short biographies - .pdf file
Terms of reference - .pdf file

Recent Biotechnology Reporting

Report Number	Title of Report	Date
CA0011	New Expert Scientific Panel Formed	2/8/00
CA0012	Current Canadian Regulatory Framework	2/8/00
CA0013	State of Biotechnology Debate in Canada	2/9/00
CA0066	Alternatives to Roundup Will Be Available	5/17/00
CA0136	Canada Plans GMO Environmental Impact Project	9/12/00
CA0145	GOC Defends Biotechnology	9/19/00

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